SUMMARY OF SAFETY and EFFECTIVENESS

Instrument Safety:

- Ultrasound signals are emitted at power levels below FDA recommended maximum exposure limits of 720 mW/cm².
- The Nicolet VersaLab is labeled for use by or on order of a physician.
- The Nicolet VersaLab is a DC rechargeable battery/DC powered device.

Good Clinical Practice dictates that ultrasound equipment, including the Nicolet VersaLab, should be operated at power levels As Low As Reasonably Achievable [ALARA]. This means that the operator uses Doppler power levels no higher that necessary to obtain blood-flow information that is adequate to make clinical judgements. The Nicolet VersaLab employs fixed [not adjustable] CW Doppler power levels that are pre-set at a limit below the maximum allowable of 720mw/cm²; therefore, the ALARA condition is always met. There are hardware levels controlling the power as well as redundant software controls.

Ultrasound Safety:

The American Institute of Ultrasound in Medicine has issued the following statement concerning the safety of ultrasound:

"No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweighs the risks, if any, that may be present".



MAR - 9 2001

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. David W. Wagner Director, Quality Assurance and Regulatory Affairs Nicolet Vascular, Inc. 6355 Joyce Drive GOLDEN CO 80403

Re: K010521

Trade Name: Nicolet VersaLab

Regulatory Class: II/21 CFR 892.1540/21 CFR 870.2880

Product Code: 90 JAF/90 JOP Dated: February 15, 2001 Received: February 22, 2001

Dear Mr. Wagner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Nicolet VersaLab, as described in your premarket notification:

Transducer Model Numbers:

4 MHz (CWD) 8 MHz (CWD)

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded. The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Sain a. Signom
David A. Segerson

Acting Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Prescription Use___

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation										
	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Cognitioned (specify)	Other (specify)		
Ophthalmic												
Fetal				<u> </u>					1 . 9	ļ		
Abdominal								•	 	<u> </u>		
Intraoperative (specify)		<u> </u>		ļ	 				<u> </u>	<u>'</u>		
Intraoperative Neurological		<u> </u>						ļ	<u> </u>	-		
Pediatric	<u> </u>	<u>L.</u>	<u> </u>	<u> </u>	ļ					 		
Small Organ (specify)				<u> </u>	<u> </u>				1			
Neonatal Cephalic	<u>L</u>								1 9			
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Transrectal			<u> </u>	<u> </u>	<u> </u>				1. 1			
Transvaginal						<u> </u>			1 4			
Transurethral									 }	-		
Intravascular									1			
Peripheral Vascular				<u> </u>	N			<u> </u>	1			
Laparoscopic					<u></u>				<u> </u>	<u> </u>		
Musculo-skeletal Conventional												
Musculo-skeletal Superficial								<u> </u>	1			
Other (specify)									<u> </u>	<u> </u>		
N= new indication; P= Additional Comments: AND SMH	N	<	XX	(TF	W	Will	ZES LP	A31	<u> </u>	HZ		

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	ultrasound imaging or fluid flow analysis of the human body as follows: Mode of Operation									
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Intraoperative Neurological	<u> </u>	1	↓		 		ļ		1	1
Pediatric	<u> </u>	_		 	-			-	+	
Small Organ (specify)								-	1	
Neonatal Cephalic	<u> </u>									
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Cardiac			1_	+-	-			1	* * *	
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Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Disappetic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	Α	В	М	PWD	CWD	Color Dappler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify	
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Fetal				ļ	ļ				-	-	
Abdominal					<u> </u>				1 1/4	1	
intraoperative (specify)			<u> </u>		<u> </u>				1		
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Neonatal Cephalic							<u> </u>	 	1	 	
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Laparoscopic											
Musculo-skeletal Conventional									1		
Musculo-skeletal Superficial									\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \		
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